It’s the BD stent/
Frequently Asked Questions

What is the BD stent?
• The BD stent is an oesophageal stent made from polydioxanone, a biodegradable surgical suture material that will completely degrade approximately 11-12 weeks after insertion (pH dependent).
• Radial force is maintained for approximately 6-8 weeks helping facilitate long-term stricture remodelling.
• The hydrolytic degradation process of PDS material involves partial bio absorption and natural passage through the digestive tract.

What is the BD Stent Indicated for?
• The BD stent is indicated for patients aged 18 and older for the management of mid to lower-third refractory benign oesophageal strictures.
• It is contraindicated for malignant strictures or for strictures in the upper third of the oesophagus requiring position of the stent within 2cm from the cricopharyngeal muscle. If it is used in the upper third of the oesophagus, there is an increased risk to patients of mucosal hyperplasia. Please check product IFUs for a full list of contraindications.
• UK Medical advises against using the BD stent for strictures in the lower third of the oesophagus which would result in any part of the BD stent sat across the GOJ. This is because of increased risk of stent migration as well as the stent degrading more rapidly due to exposure to gastric fluids. Consider the HV+ stent instead.

Why do I have to load the BD stent?
• The polydioxanone material exhibits plastic deformation and if compressed for a long period of time will not return to its most expanded state. Therefore, the BD stent must be compressed into the delivery system just before the implantation procedure.

How do I load the BD stent?
• UK Medical provides a comprehensive ‘step-by-step’ guide to loading the BD stent which can be requested as a PDF or a laminated print. Please contact Dani Hammerton, Product Manager for the ELLA range of oesophageal stents at Danielle.hammerton@ukmedical.com. Alternatively, please see the product IFUs. There is also a video available at: https://youtu.be/jcPN5U5e7JM as well as a troubleshooting guide on request. Departmental training by your local UK Medical Area Business Manager (ABM) can also be arranged.

Does the BD stent cause pain to patients?
• The BD stent has an associated misconception of causing pain. Due to the inherent nature of the types of strictures the BD stent is indicated for (benign, tight, fibrous strictures) they can be more painful to dilate as opposed to other types. Patients should be aware that the BD stent will continue

Additional information?
If you would like further assistance with using our biodegradable stent, or need advice on how to order, please call us on: 0114 268 8880
to expand for a period of up to 48 hours to its fully dilated state and that they may experience discomfort or pain within this period. It is important that the relevant clinician appropriately manages any pain on a case by case basis.

When should I use the BD stent?
• The BSG ‘UK guidelines on oesophageal dilatation in clinical practice’ recommends using the biodegradable stent to reduce the frequency of serial dilatation in selected patients. Balloon dilatation should be considered as refractory after 3 attempts and a BD oesophageal stent considered. In the largest study to date, sequential placement of a first, second and then third biodegradable stent resulted in a median dysphagia free period of 90, 55 and 106 days respectively although wasn’t a permanent solution to dysphagia.

Which size BD stent should I use?
• A complete diagnostic evaluation must be performed prior to use of the device to determine appropriate stent dimensions. The most commonly used BD stent size is 25mm diameter and 8cm length. The 20mm diameter should be considered for patients who have a smaller than usual anatomy or low tolerance to pain / discomfort. The 25mm stent will provide the highest radial force after a longer time in situ. The ends (flares) of the stent must be placed beyond the ends of the stricture i.e. within healthy tissue to promote epithelisation. Allow at least 1cm of length at either side of the stricture. Prior to releasing the stent from the delivery system, position the distal end of the compressed stent inside the delivery system at least 2cm beyond the lower margin of the stricture. The RO ring on the distal end of the delivery system helps with proper positioning before stent release. The stent shortening upon deployment should be taken into account, please see product IFUs for shortening charts. Stent shortening after releasing from the delivery system:

<table>
<thead>
<tr>
<th>Stent Length</th>
<th>18mm</th>
<th>20mm</th>
<th>23mm</th>
<th>25mm</th>
</tr>
</thead>
<tbody>
<tr>
<td>% shortening after releasing from the delivery system</td>
<td>35%</td>
<td>42%</td>
<td>48%</td>
<td>50%</td>
</tr>
</tbody>
</table>

Should I dilate the stricture before the implantation procedure?
• The delivery system is of a comparable diameter to a typical scope at 9.4mm or 28Fr. If the stricture is impassable with the gastroscope, compliant balloon dilatation initially up to 10mm is recommended (BSG Guidelines). It is not recommended to dilate further than this as there is an increased risk to the patient of perforation or stent migration if the stricture doesn’t rebound quickly.

What happens to the olive on deployment?
• The olive forms a flexible cone preventing damage to the oesophageal wall during insertion of the delivery system into the oesophagus. At the beginning of stent deployment, the olive automatically splits into 2 pieces. The olive pieces will be passed naturally by the patient.

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Any patient advice post-implantation of the BD stent?

- Patients with an implanted stent should eat well chewed food and drink sufficient liquids with meals. Obstruction of the stent by food may happen when the patient does not follow the diet discipline. Obstruction can be released by an appropriate endoscopic tool.

Disclaimer

- Use of Oesophageal Stents may result in harm to patients and negative outcomes. UK Medical Ltd accepts no liability for the content of this manual or the consequences of any actions taken on the basis of the information provided.
- Complications that can be associated with the stent implantation can include but not be limited to:
  - Stent misplacement; stent migration; inadequate length of stent; bleeding/haemorrhage; fever; infection; perforation; trachea or tracheoesophageal fistula; laceration; airway compression; ulceration or erosion of oesophageal wall; mucosal hyperplasia; stricture formation; retrosternal chest pain; nausea; vomiting; food bolus impaction; allergic reaction.

Purpose

- This document has been designed to provide information to clinicians using ELLA Oesophageal Stents in clinical practice. Where possible the information provided has been gathered from research evidence, however where this is not available, information is provided using expert opinion and from BSG or GUT guidelines.
- Information regarding insertion is available in another document and during device insertion sessions
- Information regarding care and maintenance is available as a separate document and training sessions available from UK Medical Ltd
- Patient information is available in a separate document from UK Medical Ltd